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On October 16, 2002

By: Mark B. Floyd
Mark B. Floyd, Reg. No. 41,022

PATENT
Docket No.: 020048-003330US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

McMillan et al.

Application No.: 09/808,877

Filed: March 14, 2001

For: COMPUTER PROGRAM PRODUCT FOR QUANTITATIVE ANALYSIS OF A NUCLEIC ACID AMPLIFICATION REACTION

Examiner:. Not Yet Assigned

Art Unit: 1655

TRANSMITTAL

Commissioner for Patents
Washington, DC 20231

Dear Sir:

TRANSMITTAL LETTER

Transmitted herewith for filing in the above-entitled patent application are the following:

1. Preliminary Amendment
2. 37 CFR §1.607 Request To Provoke Interference With Patent
3. Return receipt postcard

Applicants believe there is no additional fee required under 37 CFR §1.16 or §1.17.

By: Mark B. Floyd
Mark B. Floyd
Agent for Applicants
Registration No. 41,022

Date: October 16, 2002

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By: Mark B. Floyd
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#6 Plunkett 11/5/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

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For: COMPUTER PROGRAM PRODUCT FOR QUANTITATIVE ANALYSIS OF A NUCLEIC ACID AMPLIFICATION REACTION

Examiner:. Not assigned

Art Unit: 1655

37 CFR §1.607 REQUEST TO PROVOKE INTERFERENCE WITH PATENT

Commissioner for Patents
Washington, DC 20231

Sir:

Applicants hereby request that an interference be declared pursuant to 37 CFR §1.607 between the present application and the below identified unexpired U.S. Patent No. 6,303,305 B1 (the "'305 patent"). Applicants claim substantially the same subject matter as the claims of the '305 patent. The subject matter of the claims of the '305 patent was invented by Applicants prior to the effective filing date of the '305 patent.

1. The unexpired patent is U.S. Patent No. 6,303,305 B1, "METHOD FOR QUANTIFICATION OF AN ANALYTE", Wittwer, Carl T. et al., issued on October 16, 2001.

2. U.S. Patent No. 6,303,305 has a filing date of March 30, 1999. The present application was filed on March 14, 2001 claiming priority from U.S.S.N. 09/562,195 filed May 1, 2000.

Since the present application has a filing date more than three months after that of the application that matured into the '305 patent, Applicants will submit evidence that they are prima facie entitled to judgment relative to the patentee, as required under 37 CFR §1.608(b).

3. Pursuant to 37 CFR §1.607(a)(2), Applicants present the following proposed Counts:

Count 1

A method for quantification of the concentration of a nucleic acid in a sample, comprising the steps of:

a) mixing the sample with an amplification reagent;

b) amplifying at least one nucleic acid sequence in the sample to create a nucleic acid amplification product;

c) determining the amount of the nucleic acid amplification product as a function of amplification reaction time;

d) calculating a derivative of said function;

e) determining the maximum of said derivative; and

f) calculating from said maximum the initial concentration of the nucleic acid sequence in the sample.

Count 2

A method for quantification of the concentration of a nucleic acid in a sample, comprising the steps of:

a) mixing the sample with an amplification reagent;

b) amplifying at least one nucleic acid sequence in the sample to create a nucleic acid amplification product;

c) determining the amount of the nucleic acid amplification product as a function of amplification reaction time;

d) calculating the second derivative of said function;

e) determining the maximum of said second derivative; and

f) calculating from said maximum the initial concentration of the nucleic acid sequence in the sample.

Count 3

A method for quantification of the concentration of a nucleic acid in a test sample, comprising the steps of:

a) mixing the test sample with an amplification reagent;

b) amplifying at least one nucleic acid sequence in the test sample by a process comprising the step of subjecting the test sample to a number of amplification cycles to create a nucleic acid amplification product;

c) determining a value corresponding to the relative amount of the nucleic acid amplification product for each amplification cycle to generate a data set;

d) generating a function from said data set;

e) calculating a derivative of said function;

f) determining a fractional cycle number corresponding to a maximum of said derivative;

g) obtaining a calibration curve generated using steps a-e on a plurality of additional nucleic acid calibration samples, each additional calibration sample having a known concentration of the nucleic acid sequence; and

h) determining the initial concentration of the nucleic acid sequence in the test sample using the calibration curve.

4. Applicants submit that claims 1-7 and 9-13 of the '305 patent correspond to the proposed Count 1.

5. Applicants submit that Claims 45-55 of the present application correspond to the proposed Count 1. Claims 45-55 are added via the amendment filed herewith within one year of the grant of the '305 patent.

6. Applicants submit that claim 14 of the '305 patent corresponds to the proposed Count 2.

7. Applicants submit that Claim 56 of the present application corresponds to the proposed Count 2. Claim 56 is added via the amendment filed herewith within one year of the grant of the '305 patent.

8. Applicants submit that claim 15 of the '305 patent corresponds to the proposed Count 3.

9. Applicants submit that Claim 57 of the present application corresponds to the proposed Count 3. Claim 57 is added via the amendment filed herewith within one year of the grant of the '305 patent.

10. In accordance with 37 CFR §6.107(a)(5), the claims 45-57 may be specifically applied to applicants' disclosure as follows:

	New Claims	**Applicants' Disclosure**
45.	A method for quantification of the concentration of a nucleic acid in a sample, comprising the steps of:	Page 19, lines 23-25; Page 65, line 32 through page 66 line 2.
	a) mixing the sample with an amplification reagent;	Page 67, lines 10-25; Page 97, lines 24-26.
	b) amplifying at least one nucleic acid sequence in the sample to create a nucleic acid amplification product;	Page 66, lines 2-29; page 98, lines 14-18.
	c) determining the amount of the nucleic acid amplification product as a function of amplification reaction time;	Page 7, lines 8-14; page 8, lines 10-16; Page 74 line 8 through page 84 line 23.
	d) calculating a derivative of said function;	Page 7, lines 14-15; page 8 line 17; page 10 line 6; page 83 line 32 through page 96 line 22.
	e) determining the maximum of said derivative;	Page 83 line 32 through page 84 line 16; Page 90, lines 11-29; Page 93 line 16 through page 96 line 22.

	f) calculating from said maximum the initial concentration of the nucleic acid sequence in the sample.	Page 96 line 23 through page 99 line 16.
46	The method of claim 45, wherein during one phase of the amplification reaction the amount of amplification product increases progressively and wherein after said progressive phase, the rate of amplification decreases.	Page 83, lines 10-31.
47	The method of claim 45, wherein the amount of the amplification product is determined during a logarithmic growth phase of the amplification.	Page 83, lines 16-31.
48	The method of claim 45, wherein the amplification product is detected by means of fluorescence.	Page 48, lines 5-12.
49	The method of claim 46, wherein the amplification is obtained by a polymerase chain reaction and the amplification product is detected by an intercalating dye.	Page 48, lines 30-32; page 66, lines 2-10.
50	The method of claim 48, wherein amplification is obtained by a polymerase chain reaction and the amplification product is detected by two polynucleotide probes, each labeled with a fluorescent entity, such that when both probes are hybridized to one strand of the nucleic acid amplification product, fluorescence resonance energy transfer occurs between the two fluorescent entities.	Page 49, lines 9-16; page 66, lines 2-10.

51	The method of claim 47, wherein said derivative is calculated by a mathematical fit.	Page 105, lines 20-25.
52	The method of claim 51 wherein the amplification product is detected by means of fluorescence.	Page 48, lines 5-12.
53	The method of claim 51, wherein the amplification is obtained by a polymerase chain reaction and the amplification product is detected by an intercalating dye.	Page 48, lines 30-33; page 66, lines 2-10.
54	The method of claim 45, wherein the step of calculating the derivative of said function comprises calculating the second derivative.	Page 83 line 32 through page 84 line 16.
55	The method of claim 45, wherein the step of calculating the derivative of said function comprises calculating, the first derivative.	Page 93 line 16 through page 96 line 22.
56.	A method for quantification of the concentration of a nucleic acid in a sample, comprising the steps of:	Page 19, lines 23-25; Page 65, line 32 through page 66 line 2.
	a) mixing the sample with an amplification reagent;	Page 67, lines 10-25; Page 97, lines 24-26.
	b) amplifying at least one nucleic acid sequence in the sample to create a nucleic acid amplification product;	Page 66, lines 2-29; page 98, lines 14-18.

	c) determining the amount of the nucleic acid amplification product as a function of amplification reaction time;	Page 7, lines 8-14; page 8, lines 10-16; Page 74 line 8 through page 84 line 23.
	d) calculating the second derivative of said function;	Page 83 line 32 through page 84 line 16.
	e) determining the maximum of said second derivative; and	Page 83 line 32 through page 84 line 16; Page 90, lines 11-29
	f) calculating from said maximum the initial concentration of the nucleic acid sequence in the sample.	Page 10 lines 9-17; Page 96 line 23 through page 99 line 16.
57	A method for quantification of the concentration of a nucleic acid in a test sample, comprising the steps of:	Page 19, lines 23-25; Page 65, line 32 through page 66 line 2.
	a) mixing the test sample with an amplification reagent;	Page 67, lines 10-25; Page 97, lines 24-26.
	b) amplifying at least one nucleic acid sequence in the test sample by a process comprising the step of subjecting the test sample to a number of amplification cycles to create a nucleic acid amplification product;	Page 66, lines 2-13;
	c) determining a value corresponding to the relative amount of the nucleic acid amplification product for each amplification cycle to generate a data set;	Page 7, lines 8-18; Page 74 line 8 through page 84 line 23;
	d) generating a function from said data set;	Page 83 line 10 through page 84 line 23; Page 105, lines 20-25.

	e) calculating a derivative of said function;	Page 7, lines 14-15; page 8 line 17; page 10 line 6; page 83 line 32 through page 84 line 23; Page 105, lines 20-25.
	f) determining a fractional cycle number corresponding to a maximum of said derivative;	Page 7 lines 16-32; page 83 line 32 through page 84 line 23;
	g) obtaining a calibration curve generated using steps a-e on a plurality of additional nucleic acid calibration samples, each additional calibration sample having a known concentration of the nucleic acid sequence; and	Page 97 line 13 through page 99 line 16.
	h) determining the initial concentration of the nucleic acid sequence in the test sample using the calibration curve.	Page 96 line 23 through page 99 line 16.

11. Applicants will comply with any additional requirements of 37 CFR §1.607 in due course and it is respectfully requested that Applicants' attorneys be contacted prior to issuance of any Office Action.

Respectfully submitted,

By: Mark B. Floyd
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Date: October 16, 2002